IN THE MATTER OF	*	
NON-PRIMARY PERCUTANEOUS	*	
CORONARY INTERVENTION	*	
RESEARCH WAIVER REVIEW	*	
	*	
	*	**BEFORE THE MARYLAND**
Baltimore Washington Medical Center	*	
Docket No. 08-02-0029 NPRW	*	**HEALTH CARE COMMISSION**
	*	
Holy Cross Hospital	*	
Docket No. 08-15-0033 NPRW	*	
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Johns Hopkins Bayview Medical Center	*	
Docket No. 08-24-0030 NPRW	*	
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COMMISSION DECISION

June 18, 2009

Table of Contents

I. INTRODUCTION

On February 4, 2008, the Maryland Health Care Commission received applications from seven community hospitals for a waiver to provide non-primary (elective) percutaneous coronary intervention (npPCI) services as part of a study of the safety and effectiveness of such procedures when performed in hospitals without on-site cardiac surgery. Applications were received from Anne Arundel Medical Center (AAMC), Baltimore Washington Medical Center (BWMC), Johns Hopkins Bayview Medical Center (JHBMC, or Hopkins Bayview), and St. Agnes Hospital (SAH) in the Metropolitan Baltimore Regional Service Area, and Holy Cross Hospital (HCH), Shady Grove Adventist Hospital (SGAH), and Southern Maryland Hospital Center (SMHC) in the Metropolitan Washington Regional Service Area.

On October 14, 2008, the Commission received applications from Frederick Memorial Hospital (FMH) and Washington County Hospital (WCH), two community hospitals in the Western Maryland Regional Service Area, for waivers to provide npPCI services.

State Health Plan: Cardiac Surgery and Percutaneous Coronary Intervention Services

In Maryland, cardiac surgery and percutaneous coronary intervention (PCI) are governed by State Health Plan chapter COMAR 10.24.17 (the "Chapter"). Policy 5.0 of the Chapter restricts the provision of PCI services to hospitals with on-site cardiac surgical backup, except as provided for by Policies 5.1 and 5.3. Policy 5.1 allows hospitals without on-site cardiac surgical backup that meet requirements set forth in COMAR 10.24.17, Table A-1, to obtain a waiver to perform primary (emergency) PCI. The Commission's primary PCI (pPCI) waiver program began in 2006. Currently, 13 Maryland hospitals without on-site cardiac surgical backup have waivers to perform pPCI. Ten Maryland hospitals provide both pPCI and npPCI in conjunction with on-site cardiac surgery programs.

Policy 5.3 empowers the Commission to grant waivers to hospitals without on-site cardiac surgery to participate in research studies that "advance the understanding of how cardiac care services should be organized to improve outcomes." The Chapter recognizes the need for research to assess the safety and efficacy of non-primary PCI services among defined patient groups when performed in hospitals without on-site cardiac surgery. Policy 5.3 also requires the appointment of a Research Proposal Review Committee to advise the Commission on research proposals requesting a waiver under the Chapter.

In 2005, the Commission received a proposal from the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) to engage Maryland hospitals without on-site cardiac surgery in a research study of the safety and efficacy of npPCI performed in such facilities. The Commission convened a Research Proposal Review Committee comprised of cardiologists, epidemiologists, and others, drawn from Maryland as well as other states, to review the proposal.

Coincident with the completion of the Committee's work,[1] the principal investigator withdrew the proposal.

The C-PORT group submitted a revised proposal to the Commission in 2006, which was reviewed by the reconstituted Research Proposal Review Committee. The Committee found the proposal to be scientifically acceptable, but expressed reservations about the expected rates of patient retention and adverse events, and the potential for patient selection or other bias to be introduced into the study.[2] The Executive Director of the Commission, upon review of the Committee's report, recommended the establishment of a waiver program that would permit Maryland hospitals without on-site cardiac surgery to participate in the study under the Commission's oversight.[3]

The Commission accepted the Executive Director's recommendations on April 19, 2007, and directed Commission staff to draft regulations to implement the recommendations. The resulting regulations, COMAR 10.24.05, established a waiver program under which Maryland hospitals without on-site cardiac surgery could apply to participate in the C-PORT non-primary angioplasty research study (C-PORT E). The regulations provide for a comparative review process for granting time-limited waivers to a limited number of hospitals meeting specific eligibility requirements, and criteria for both maintaining and relinquishing granted waivers.

The Joint Committee on Administrative, Executive, and Legislative Review granted emergency status to amendments to COMAR 10.24.05 to increase the number of npPCI waiver hospitals from no more than six to no more than nine, and limit eligibility to those hospitals whose applications were docketed and pending as of March 18, 2009. Emergency status began on April 11, 2009, with an expiration date of September 14, 2009. Notice of the Commission's proposed action to amend the regulations was published in the *Maryland Register* on April 24, 2009, giving the public an opportunity to comment on the proposal before the Commission takes final action on the proposed amendment.

C-PORT Non-primary Angioplasty Study Summary

The C-PORT E study will compare the outcomes of npPCI procedures performed in hospitals without on-site cardiac surgery to the outcomes of those performed in hospitals with on-site cardiac surgery. Designed as a non-inferiority clinical trial, the study tests the hypothesis that mortality at six weeks and MACE (major adverse cardiac events, i.e., death, myocardial infarction and/or target vessel revascularization) at nine months post-procedure do not differ between hospitals with and without on-site cardiac surgery. In order for the hypothesis to be accepted, non-inferiority must be demonstrated with regard to both mortality and MACE.

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[1] Maryland Health Care Commission. Report of the Research Proposal Review Committee – Review of the Scientific Merit of the Atlantic C-PORT Trial: Proposed Non-Primary Percutaneous Coronary Intervention (PCI) Study, Version 2.5, March 22, 2005. Baltimore, MD, August 16, 2005.

[2] Maryland Health Care Commission. Research Proposal Review Committee – Report 2: Scientific Review of the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Proposed Non-Primary Percutaneous Coronary Intervention (PCI) Study, Version 3.0, March 29, 2006. Baltimore, MD, March 30, 2007.

[3] Maryland Health Care Commission. Executive Director's Recommendation: Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Proposal to Study Non-Primary (Elective) PCI Performed in Maryland Hospitals Without On-Site Cardiac Surgery. Baltimore, MD, April 13, 2007.

Because of the type of study design employed and clinically-based assumptions about expected mortality and MACE event rates, a total of 18,360 patients who meet strictly defined eligibility criteria are required for the successful completion of the study. Of this number, 75% (13,770) will receive npPCI at hospitals without on-site cardiac surgery. The other 25% (4,590) will be randomly assigned to receive npPCI at hospitals with on-site cardiac surgery. Consequently, the study is recruiting patients from multiple hospitals in multiple states. The study includes hospitals in both urban and non-urban areas that represent diverse patient populations, patient volumes, and varying proximities to tertiary care centers.

Patient recruitment for the C-PORT E study began at a single hospital in Alabama on September 2, 2005. As of May 26, 2009, 45 hospitals in 10 states have randomized 10,562 patients in the study.[4] More than 90% of the patients who were approached gave their consent to participate in the study. The four Maryland metropolitan hospitals approved in September 2008 began randomizing patients in January 2009. The two Western Maryland hospitals were approved in March 2009.

II. BACKGROUND

The npPCI research waiver application process began on February 4, 2008, when the Commission staff started the comparative review of applications from four hospitals in the Metropolitan Baltimore and from three hospitals in the Metropolitan Washington Regional Planning Areas. The Executive Director's Recommendation,[5] as modified, on the metropolitan hospitals' applications was accepted by the Commission during its public meeting on September 18, 2008. The Commission voted to issue waivers to Anne Arundel Medical Center and St. Agnes Hospital in the Metropolitan Baltimore Regional Service Area, and to Shady Grove Adventist Hospital and Southern Maryland Hospital Center in the Metropolitan Washington Regional Planning Area. The Commission took no action on the applications from Baltimore Washington Medical Center, Johns Hopkins Bayview Medical Center, and Holy Cross Hospital pending the outcome of the second phase of the application process, i.e., the comparative review of applications from hospitals in the Western Maryland Regional Service Area. The Commission held two waivers in abeyance. If the remaining two waivers available under the regulations were not awarded in the review of applications from Western Maryland, the Commission stated its intention to review the case volumes of Baltimore Washington Medical Center, Holy Cross Hospital, and Johns Hopkins Bayview Medical Center and take action so that all six research waivers are awarded. The maximum number of waivers has increased to nine, and this review involves the next phase of the application process.

Two pending applicants are in the Metropolitan Baltimore Regional Service Area. BWMC has 298 acute care beds and is located in Anne Arundel County at 301 Hospital Drive, Glen Burnie. Located in Baltimore City, JHBMC has 345 beds and is located at 4940 Eastern Avenue. The third pending applicant is in the Metropolitan Washington Regional Service Area.

[4] Information about the status of the study as of May 26, 2009 was provided by the Principal Investigator, Thomas Aversano, M.D. on May 29, 2009.

[5] Maryland Health Care Commission. Partial Final Decision in the Matter of Non-Primary Percutaneous Coronary Intervention Research Waiver Review. Baltimore, MD, September 18, 2008.

HCH is located in Montgomery County at 1500 Forest Glen Avenue, Silver Spring and has 408 beds. All of the applicants, BWMC, HCH, and JHBMC, are teaching hospitals.

III. APPLICATION REVIEW AND ANALYSIS

COMAR 10.24.05.04A(2)(c): ***For minimum volumes, an applicant shall document that it will meet and maintain a minimum volume of 100 PCI procedures during the first year of its waiver, and 200 PCI procedures during the second year of its waiver…***

The C-PORT E study of the safety and efficacy of npPCI when performed in hospitals without cardiac surgical backup began in other states in 2005. After diagnostic cardiac catheterization (Dx cath) and prior to patient randomization, specific post-catheterization criteria are used to determine whether the patient is eligible for npPCI under the study protocol. Patients with ST-elevation myocardial infarction (STEMI) are excluded from the study prior to catheterization; post-catheterization exclusion criteria include the patient's need for coronary artery bypass surgery or if the patient is considered to be at high procedural risk. Based on the experience of hospitals in other states, the C-PORT E Principal Investigator advised the hospitals prior to filing their applications that, on average, 30% of diagnostic catheterizations result in npPCI treatment. In addition, the study protocol requires that participating hospitals randomly assign 25% of eligible patients to tertiary care centers for the intervention. Applicants also were advised to document the number of patients being sent to other facilities for catheterizations and to document anticipated changes in physician referral patterns when assessing the hospital's ability to recruit patients into the study. The information provided by the applicants is described below.

Responses of Applicants

BWMC

BWMC reported that the hospital's pPCI and diagnostic cardiac catheterization volume in calendar year 2008 was 124 cases with diagnostic cardiac cath and pPCI, and 127 cases with diagnostic cath only. If 30% of these cases had resulted in npPCI, with the hospital retaining 75% of the cases, BWMC calculated that the hospital would have an estimated PCI volume of 153 (29 npPCIs plus 124 pPCIs).

BWMC cited three sources of data that the hospital used to determine the number of patients who were previously referred to other hospitals but would be expected to be referred to BWMC for diagnostic catheterization: (1) transfers from the BWMC ED who received a diagnostic cath and/or npPCI at another hospital; (2) inpatients at BWMC who were transferred to another hospital and received a diagnostic cath and/or npPCI; and (3) patients who went to another hospital for diagnostic cath and/or npPCI directly from the offices of physicians who have committed to refer patients to BWMC. BWMC stated that the hospital analyzed the list of patients who had a cardiac cath performed by one of the interventional cardiologists who will participate in the npPCI study at BWMC; the hospital eliminated transferred ED patients and inpatients from that list (those sent directly from the physicians' offices).

With regard to ED transfers, BWMC's emergency department obtained data on each cardiac patient, including name, date of birth, Social Security number, the hospital to which the patient was transferred, why the patient was transferred, if cardiac cath was performed, whether the procedure was diagnostic or interventional, and which physician performed the procedure. The hospital removed eight cases that also appeared on the admitted/transferred list. Of the 86 patients remaining on the ED transfer list, 71 patients were transferred to the University of Maryland Medical Center (UMMC). UMMC and BWMC are hospital members of the University of Maryland Medical System. A chart review was performed on each patient sent to UMMC. BWMC reported that 50 of those patients received cardiac catheterization; BWMC's four physicians performed 28 of the cath cases. According to BWMC, potentially 19 of the remaining 22 cath cases could have been done at BWMC if npPCI were available; the other three cases were performed by physicians who are on BWMC's medical staff but do not participate in the hospital's pPCI program. BWMC stated that the transfer notes of 7 of 10 patients who were transferred to Union Memorial Hospital (UMH) included documentation that the patient was sent for cardiac cath; 6 of those patients could potentially have been treated at BWMC under the C-PORT E trial.

BWMC manually cross-referenced the hospital's CY2008 inpatient data with the procedure logs of the four physicians who participate in the pPCI program at BWMC. The eight duplicate cases that were removed from the ED list were left on the admitted/transferred list. Of the 305 patients with a diagnosis of ischemic heart disease who were transferred from BWMC to another acute care hospital, 166 patients were taken to the cardiac cath lab by these four physicians. Of the remaining 139 patients, 81 patients transferred to UMMC did not go to the cath lab, and 58 patients were transferred to other facilities.

BWMC stated that the four interventional cardiologists who perform pPCI at BWMC perform most of their diagnostic catheterization and npPCI cases at UMMC and, on occasion, at Union Memorial Hospital. According to BWMC, the physicians provided their own data on the numbers of cases performed at UMH; BWMC accessed the electronic medical records data at BWMC and cardiac cath lab case logs at UMMC to confirm the physicians' data on cases at those hospitals.

BWMC noted that the hospital also evaluated the payors for each patient to determine whether any restrictions would preclude patients from having a diagnostic cath or npPCI performed at BWMC. According to the hospital, the only third-party payors with such restrictions are Kaiser and United Healthcare's MDIPA and Optimum Choice products. BWMC stated that Kaiser has an exclusive relationship with a cardiology group that does not practice at BWMC; MDIPA and Optimum Choice require their members to use "Cardiac Premium Program Designated facilities". In CY2008, the hospital transferred five patients with these insurance plans to other hospitals for diagnostic cath or npPCI.

In the application that the hospital submitted in February 2008, BWMC provided supporting correspondence from the two largest cardiology practices at the hospital, representing 14 cardiologists. Both practices direct npPCI patients to UMMC, which is BWMC's designated tertiary care center partner. In addition to the letters of commitment that the hospital included in its original application, BWMC provided letters dated April 27, 2009, expressing continued

support and confirming the intentions of two cardiology groups to refer patients to BWMC as part of the C-PORT E study. Arundel Heart Associates, P.A. has six cardiologists; the practice has its only office in BWMC's ZIP code. The Heart Center of Northern Anne Arundel County, P.A. includes eight cardiologists. The main office of this practice is also located in BWMC's ZIP code; a small satellite office is located on the campus of Harbor Hospital, which does not perform PCI.

Arundel Heart Associates identified a total of 572 cases that the practice referred to hospitals other than BWMC: 395 diagnostic catheterizations (235 at UMMC, and 160 at other hospitals), and 177 npPCI cases (105 at UMMC, and 72 at other hospitals). According to the six cardiologists, "virtually all of these patients would have agreed to participate in the C-PORT E study if that option had been available when these cases had been performed." The group anticipates no insurance-related problems or patient concerns that would have an impact on the program's success at BWMC, noting that patients "can receive their care closer to home, unless they are randomized to the UMMC-site."

The Heart Center of Northern Anne Arundel County identified a total of 773 "cases to be referred to BWMC": 541 diagnostic caths (516 at UMMC, and 25 at other hospitals), and 232 npPCIs (216 at UMMC, and 16 at other hospitals). Likewise, the members of the Heart Center of Northern Anne Arundel County "believe that virtually all of these patients" would have preferred to receive their care close to home and would have agreed to participate in the C-PORT E study.

According to BWMC, the number of additional patients expected is 1,370. The hospital stated, "In CY2008, BWMC's cardiologists who have committed to participate in the npPCI study performed 1,091 diagnostic catheterizations at the University of Maryland Medical Center and another 279 at other hospitals." The total figure consists of 47 ED transfers to UMMC (25 diagnostic caths, and 22 cath and PCI cases); 166 inpatient transfers to UMMC (97 and 69 cases, respectively); 878 elective cases at UMMC (640 diagnostic caths, and 238 patients who received cardiac cath and intervention); and 279 patients who received procedures in other hospitals (191 and 88 cases, respectively). After the patients are randomized, the estimated additional npPCI volume at BWMC would be 308 cases. When added to the 2008 data for pPCIs and diagnostic caths performed at BWMC, the hospital estimated that it would perform a total of 461 PCI procedures.

HCH

Using data from the Maryland STEMI Primary PCI Data Registry and the hospital's cardiac catheterization laboratory procedure log, HCH reported that, during 2008, the hospital performed 74 pPCI procedures and 108 diagnostic cardiac catheterizations. Based on these volumes, HCH calculated that the hospital would have an estimated PCI volume of 98 cases.

To estimate the number of additional patients expected to be referred for diagnostic catheterizations, HCH identified the number of adult (ages 18+) inpatients and outpatients with a diagnosis of ischemic heart disease (excluding patients with a principal diagnosis of STEMI) who were transferred from HCH to another acute care hospital. This analysis, which excluded

patients who received a diagnostic catheterization prior to transfer from HCH, resulted in 123 cases that could have had a diagnostic catheterization at HCH.

HCH also identified the number of patients that the hospital expects its physicians would refer for diagnostic catheterizations if HCH were to participate in the npPCI waiver program. In letters expressing strong support of the hospital's application, HCH's four interventionalists collectively identified a total of 341 patients annually who could potentially be referred to the hospital. The analysis of each physician's patients seen at HCH excluded those patients who were transferred to another acute care hospital.

HCH estimated that, after randomization, the transferred patients and physician referrals would result in an additional 104 npPCI cases. Based on the combined sources, HCH anticipates that the hospital would perform a total of 203 PCIs.

JHBMC

JHBMC stated that, during 2008, the hospital's cardiologists performed 53 pPCI procedures and 294 diagnostic caths at JHBMC. According to JHBMC, the hospital's diagnostic cath volume would yield 66 npPCIs, for a total of 119 PCI procedures among these patients.

In addition to the 2008 volume calculation, JHBMC included the 2007 data previously supplied by the hospital as well as revised 2007 data in its filing. The hospital noted that the lower-than-usual volume of cardiac caths in 2008 was caused by a temporary closing of the lab beginning in January 2008. In addition to the cath lab, JHBMC has a lab that is used for electrophysiologic procedures (EP) as well as catheterization (the EP lab). For two months during the first quarter of 2008, the EP lab was closed to permit the installation of a bi-plane system, which experienced unexpected delays. During that period, the cath lab temporarily served as the only lab for electrophysiologic and cath procedures; it was reserved for catheterization during the mornings and for EP during the afternoons. As a result, caths that would have been performed at JHBMC were moved to JHH. Data from the Physician Reporting System showed that 382 diagnostic caths were performed at JHBMC in 2007 (an average of 96 per quarter). Based on inpatient and outpatient data reported to the Health Services Cost Review Commission, the number of diagnostic caths during the first quarter of 2009 was 84. According to JHBMC, volume dropped in the first two quarters of 2008 (53 and 64, respectively), and did not return to the normally higher levels until the third and fourth quarters of 2008 (78 and 99, respectively).

To identify the number of additional patients expected to be referred for diagnostic catheterization, JHBMC used the Physician Reporting System, a database of all cardiac catheterization reports at both Johns Hopkins Hospital (JHH) and JHBMC. JHH and JHBMC are hospital members of the Johns Hopkins Health System. JHBMC cross-referenced the list of 2,268 patients who received diagnostic catheterization at JHH in 2008 with the Electronic Patient Record database, which includes all inpatient and outpatient encounters at both JHH and JHBMC. The patient billing system provided information about patients who received treatment (admissions, doctor visits, or medical services) at JHBMC within the last three years. JHBMC reported that this analysis showed that 436 JHBMC patients were among the 2,268 patients who

received diagnostic catheterization at JHH in 2008. This figure includes patients referred by JHBMC cardiologists and other attending physicians (e.g., primary care). The hospital identified an additional 19 patients who were transferred from JHBMC to Union Memorial Hospital (UMH) for diagnostic catheterization in 2008. JHBMC estimated that the hospital will retain no less than 80% of the total of 455 patients who were referred for diagnostic catheterization.

The cardiologists at JHBMC have the option of referring patients to JHBMC or JHH for diagnostic catheterization; in cases where a non-primary PCI was anticipated, most JHBMC-based patients were referred to JHH. JHBMC submitted letters expressing the unconditional support of all referring physicians at JHBMC, and all physicians with responsibility for referral patterns and policy at JHH, including all 17 JHBMC cardiologists and 1 Physician Assistant-Certified (PA-C); Chief of the single Cardiology Division for both JHH and JHBMC; Chief of Clinical Cardiology for both JHH and JHBMC; and Chair of the Department of Medicine at JHBMC. In their letters of support, the JHBMC cardiologists and PA-C identified 244 patients referred to JHH for a diagnostic catheterization in 2008. Further, JHBMC stated, "This commitment to refer all such Hopkins Bayview patients to Hopkins Bayview for diagnostic catheterization is also supported by The Johns Hopkins Health Systems Corporation, the corporate parent of both Hopkins Bayview and JHH, which will direct that, whenever consistent with patient wishes and insurance limitations, diagnostic catheterization on Hopkins Bayview patients be performed at Hopkins Bayview."

In addition to the written commitment of referring physicians on staff at JHBMC and JHH, JHBMC submitted letters of support from physician groups and doctors with practices in JHBMC's service area. The patients identified by these physicians would be good candidates for diagnostic catheterization and represent an additional source of npPCI volume resulting from changes in referral patterns.

Johns Hopkins Community Physicians (JHCP) is a physician practice group whose offices include four within JHBMC's service area (Canton Crossing, Riverside, White Marsh, and Dundalk); the 28 physicians who provide adult internal medicine and primary care services at these offices routinely refer patients with ischemic heart disease and abnormal stress tests to area cardiologists. JHCP estimated that approximately 700 patients from these offices are referred to cardiologists at hospitals other than JHH or JHBMC. Noting that JHBMC would be the closest npPCI hospital to the four offices, JHCP stated that the practice is "confident that no fewer than 2/3 of those patients (or 467) would be seen by cardiologists at Hopkins Bayview." According to JHCP, 5% to 10% of those referrals would lead to diagnostic catheterizations, based on the practice's internal referral records.

Baltimore Medical Systems, a federally qualified health center, has three locations within JHBMC's service area (Highlandtown, Belair-Edison, and Middlesex); 20 physicians who provide adult internal medicine and primary care are located in these medical offices. Using internal referral records and the same methodology, Baltimore Medical Systems estimated that no fewer than 2/3 of its 2,579 cardiology referrals would be directed to JHBMC, the closest hospital with npPCI if approved; an estimated 5% to 10% of the referrals would undergo diagnostic catheterization.

Michelle Juaneza, M.D., of Health and Wellness Matters, Inc., is a solo practitioner who provides adult internal medicine and primary care and whose office is located an eight-minute drive from JHBMC. Dr. Juaneza estimated that she refers 25 patients annually to cardiologists for diagnostic and interventional procedures at other central Maryland hospitals, such as JHH, UMH, St. Joseph Medical Center, University of Maryland Medical Center, and Sinai Hospital. With regard to the number of patients who would have their npPCIs at JHBMC, she expressed confidence that "no fewer than 2/3 of them would."

A group practice comprised of two physicians who provide adult internal medicine and primary care estimated that the group refers 10 patients annually to cardiologists for diagnostic and interventional procedures at other central Maryland hospitals. The location of Merritt Medical Center, the group's office, is a ten-minute drive from JHBMC. The same methodology was applied to estimate how many of these 10 patients will have their npPCIs at JHBMC.

True Care Medical Group, another practice of two physicians who provide adult internal medicine and primary care, has an office that is located a five-minute drive from JHBMC. No fewer than 2/3 of the group's 350 patients now referred to cardiologists at other hospitals are expected to have their npPCIs at JHBMC.

The office of Satpal S. Dang, M.D. is located a six-minute drive from JHBMC. According to Dr. Dang, at least 2/3 of the 15 patients annually referred from that office to other hospitals in central Maryland would have their npPCIs at JHBMC.

Patient First is an outpatient facility located on the campus of JHBMC; the practice provides adult internal medicine, primary care, and urgent care. Patient First estimated that "1,000 patients annually are referred to cardiologists or the Emergency Room for cardiac evaluation to rule out an ischemic event, diagnostic catheterizations and interventional procedures." No estimate of how many of these patients would have their npPCIs at JHBMC was provided.

Analysis and Findings

Acute coronary syndrome (ACS) includes myocardial infarction (both STEMI and non-ST-elevation myocardial infarction or NSTEMI) and unstable angina (UA). In the C-PORT npPCI trial, only patients with STEMI are excluded from randomization; the study population includes patients with stable angina, unstable angina, and acute MI. The C-PORT principal investigator expects that more acute (unstable angina, NSTEMI) and fewer stable patients will be enrolled in the study. Sicker, more unstable patients (i.e., more acute MIs) tend to present at the community hospital. With regard to the management of patients with UA/NSTEMI, national guidelines indicate that, excluding patients who need urgent intervention, coronary angiography to identify the exact location and severity of a patient's coronary artery disease may be used early (i.e., immediately) or deferred (i.e., within a 12- to 48-hour period of time). Patients at high risk for mortality and recurrent ischemia should receive cardiac catheterization and revascularization within 48 hours of presentation. One study, however, found that patients with

non-ST-segment elevation acute coronary syndromes who were at high risk for predicted in-hospital mortality frequently did not receive guideline-recommended diagnostic procedures.[6]

Tables 1 and 2 show the breakdown of transferred patients with ischemic heart disease and the number who had cardiac catheterization performed prior to transfer to an acute care hospital. With a few exceptions, these patients were transferred to tertiary hospitals, based on the receiving hospitals that were identified.

Table 1. Number of Ischemic Heart Disease (IHD)[1] Patients Who Were Discharged from Applicant Hospitals to an Acute Care Hospital[2]: 2008

	Discharges					
Hospital	STEMI[3]	Other AMI[4]	UA[5]	Other IHD	Subtotal	Total
BWMC	29	141	123	134	398	427
HCH	25	53	16	37	106	131
JHBMC	6	63	5	32	100	106

Source: Health Services Cost Review Commission, Maryland Hospital Discharge Data Set, 2008.
[1]Ischemic Heart Disease (IHD) - Principal Diagnosis ICD-9 Codes 410-414
[2]Discharge to acute care hospital - Discharge Disposition Code 40
[3]STEMI - 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.81
[4]Other AMI: NSTEMI - 410.71; AMI, unspecified site (not otherwise specified) – 410.91
[5]Unstable Angina (UA) - 411.1

Table 2. Number of Ischemic Heart Disease (IHD)[1] Patients Who Received Cardiac Catheterization at the Applicant Hospitals and Were Discharged to an Acute Care Hospital[2]: 2008

	Discharges					
Hospital	STEMI[3]	Other AMI[4]	UA[5]	Other IHD	Subtotal	Total
BWMC	16	4	0	6	10	26
HCH	14	6	0	2	8	22
JHBMC	3	32	0	13	45	48

Source: Health Services Cost Review Commission, Maryland Hospital Discharge Data Set, 2008.
[1]Ischemic Heart Disease (IHD) - Principal Diagnosis ICD-9 Codes 410-414
[2]Discharge to acute care hospital - Discharge Disposition Code 40
[3]STEMI - 410.01, 410.11, 410.21, 410.31, 410.41, 410.51, 410.61, 410.81
[4]Other AMI: NSTEMI - 410.71; AMI, unspecified site (not otherwise specified) – 410.91
[5]Unstable Angina (UA) - 411.1

IHD patients who have been admitted to the hospital represent an important source of potential candidates for the npPCI study. Except for the patients with a principal diagnosis of STEMI who are undergoing an emergency procedure to treat an acute coronary artery occlusion, the C-PORT E study requires participating hospitals to approach all patients coming through the cardiac cath lab about participation in the study. For the most part, patients who present to the

[6] Roe MT, Chen, AY, Delong ER, et al. Patterns of transfer for patients with non-ST-segment elevation acute coronary syndrome from community to tertiary care hospitals. Am Heart J 2008;156:185-92.

community hospital have self-selected the facility; hence, a high percentage of patients sign the informed consent for the study.

The coronary angiography performed to identify the STEMI culprit lesion may also detect coronary narrowing of functional significance that does not require an emergency procedure. Based on these findings, the hospital may approach a STEMI patient during post-procedure hospitalization regarding participation in the elective angioplasty study. In such cases, it is usually not necessary to repeat the catheterization.

The Commission requires that a hospital receiving an npPCI research waiver perform a minimum volume of 100 PCI procedures during the first year of its waiver, and 200 PCI procedures during the second year of its waiver. As part of the waiver application, each hospital submitted information addressing how it expects to meet these requirements. Applicants that relied upon changes in physician referral patterns to meet the volume requirements were directed to provide documentation stating quantitatively how those patterns would change.

Table 3 was compiled from 2008 PCI volume and 2008 inpatient and outpatient Dx cath volume (ICD-9 procedure codes 3721, 3722, and 3723; CPT codes 93501, 93510, and 93526) for each of the applicant hospitals. These data were used to estimate the number of patients likely to be eligible for npPCI (i.e., 30% of patients undergoing Dx cath and accounting for 75% of those procedures being performed at the applicant hospital).

Table 3. Applicant Hospitals' Total PCI Volume Based on Data from the Maryland STEMI Registry and Maryland Hospital Data Sets, and Threshold Volume Based on Documented Change in Referral Patterns.

Hospital	PCI Volume Under pPCI Waiver[1]	Dx Cath Cases	Estimated npPCI Volume	npPCI Treatment Site		Total PCI Volume at Applicant Hospital Without Referrals[1]	Total PCI Volume ≥ 200 with Documented Change in Referrals
				Applicant	Tertiary Center		
BWMC	124	250[a]	75	56	19	180	Yes
HCH	74	171[b]	51	38	13	112	Yes
JHBMC	53	295[c]	89	67	22	120	Yes

Sources: Maryland Health Care Commission, 2008 STEMI Registry, March 19, 2009; Health Services Cost Review Commission, Maryland Hospital Discharge Data Set, CY 2008; Maryland Hospital Outpatient Data Set, CY 2008

[1] Total PCI cases = number of PCI cases (use of device) in 2008 plus number of estimated npPCI cases

[a] Includes 121 PCI cases with diagnostic cath coded. BWMC's discharge abstract data included 126 cases with a PCI procedure code; 5 cases had no diagnostic cath code.

[b] Includes 61 PCI cases with diagnostic cath coded. HCH's discharge abstract data included 72 cases with a PCI procedure code; 11 cases had no diagnostic cath code.

[c] Includes 37 PCI cases with diagnostic cath coded. JHBMC's discharge abstract data included 52 cases with a PCI procedure code; 15 cases had no diagnostic cath code. For two months during the first quarter of 2008, the normal capacity of the cath lab for catheterization procedures was reduced.

The Dx cath cases in Table 3 include PCI cases with diagnostic cardiac cath. The discharge abstract data show that the hospitals' coding of the cardiac catheterization (and angiocardiography) performed when the STEMI patient was taken emergently to the lab varied. An additional code for diagnostic cardiac catheterization was not assigned for 4% of the BWMC cases; 15%, HCH; and 29%, JHBMC.

Baltimore Washington Medical Center

In 2008, BWMC discharged 745 patients with ischemic heart disease (IHD), including 136 STEMI, 204 other acute myocardial infarction (AMI), 167 UA, and 238 other ischemic heart disease patients. Excluding Medicaid MCO/HMO and Medicare HMO plans, the primary health plan payer for a total of 38 patients was as follows: Kaiser (8), MAMSI (19), and United Healthcare (11).[7] Some health plans offer incentives for covered individuals to receive care from designated facilities; a facility may or may not be the hospital nearest to the individual.

BWMC expects 1,370 additional patients to be referred to the hospital for Dx cath. This figure includes all (i.e., 100%) of the diagnostic catheterizations or npPCIs performed by the hospital's four interventionalists at UMMC and other hospitals. Dx cath cases transferred from BWMC to UMMC accounted for 122 cases in 2008.

The straight line distances between BWMC and the nearest npPCI hospitals are 10.3 miles to UMMC, and 9.5 miles to St. Agnes Hospital (SAH), which is a participant in the C-PORT E study. Driving times between these hospitals during non-rush hour and rush hour conditions are 15.6 minutes and 24.6 minutes, respectively, to UMMC; and 15.2 minutes and 24.6 minutes, respectively, to SAH. Two of the Arundel Heart cardiologists who participate in the pPCI program at BWMC have interventional cardiology privileges at BWMC, UMMC, and UMH. Distance and driving times to UMH are 13.2 miles, 21.0 minutes during non-rush hour, and 33.7 minutes during rush hour. One of the two Heart Center cardiologists who participate in BWMC's pPCI program has interventional cardiology privileges at BWMC, UMMC, UMH, and Sinai Hospital, while the other interventionalist has privileges at BWMC, UMMC, and UMH. Distance and driving times to Sinai are 15.0 miles, 24.1 minutes during non-rush hour, and 38.1 minutes during rush hour. Anne Arundel Medical Center (AAMC), also a participant in the C-PORT E study, is located 11.6 miles, 22.8 minutes during non-rush hour, and 33.3 minutes during rush hour from BWMC. The extended service areas of AAMC and SAH include BWMC's ZIP code.

In 2008, BWMC had the highest pPCI volume of all waiver hospitals. If every pPCI patient were also a candidate for npPCI, BWMC would need 90 diagnostic cath cases to obtain 20 additional npPCI cases at the applicant hospital. On the other hand, if none of the pPCI patients were found to be candidates for npPCI, BWMC would need 210 diagnostic cath cases to obtain 47 additional npPCI cases at BWMC.

[7] In 2004, UnitedHealth Group and the Mid-Atlantic Medical Services, Inc. LLC (MAMSI) merged. The health plans that MAMSI offered to groups and individuals in Maryland include MD-Individual Practice Association, Inc. (M.D. IPA) and Optimum Choice, Inc. (OCI).

The number of additional cases that BWMC is expected to obtain falls within this range. BWMC is consistent with this requirement.

Holy Cross Hospital

HCH discharged 345 IHD patients; those discharges included 83 STEMI, 124 other AMI, 29 UA, and 109 other IHD patients. Kaiser (45), MAMSI (2), and United Healthcare (11) were the health plans responsible for the major portion of 58 patients' hospital expenses. In the application that the hospital submitted in February 2008, HCH provided supporting correspondence from the Chief of Cardiology, Mid-Atlantic Permanente Medical Group. The Kaiser Permanente Medical Group (Kaiser) advised HCH that the group supports the hospital's participation in the study of non-emergent PCI in hospitals without on-site cardiovascular surgery, and anticipates that some of the group's patients will opt to have needed coronary interventions performed at HCH were this to become an option.

HCH expects 123 additional Dx cath cases to result from hospital transfers (excluding STEMI patients) and 341 from physician referrals.

The straight line distances between HCH and the nearest npPCI hospitals in Maryland are 2.9 miles to Washington Adventist Hospital (WAH), and 4.2 miles to Suburban Hospital. Driving times between these hospitals during non-rush hour and rush hour conditions are 5.5 minutes and 9.0 minutes, respectively, to WAH; and 7.5 minutes and 12.7 minutes, respectively, to Suburban.

The other hospitals at which HCH's interventionalists have privileges include WAH, Suburban, Prince George's Hospital Center[8], and Southern Maryland Hospital Center, which is a C-PORT E participant, in Maryland; and George Washington University Medical Center and Washington Hospital Center in the District of Columbia. Collectively, the potential referrals to HCH represent about 35% of the four physicians' estimated annual total of patients referred to other hospitals.

In 2008, HCH increased its pPCI volume by nearly 50%. If every pPCI patient were also a candidate for npPCI, HCH would need 390 diagnostic cath cases to obtain 88 additional npPCI cases at the hospital. If none of the pPCI patients were found to be candidates for npPCI, HCH would need 450 diagnostic cath cases to obtain 101 additional npPCI cases at HCH.

The number of additional cases that HCH is expected to obtain falls within this range. HCH is consistent with this requirement.

Johns Hopkins Bayview Medical Center

The 345 IHD patients discharged from JHBMC in 2008 were comprised of 50 STEMI, 171 other AMI, 13 UA, and 111 other IHD patients. Kaiser was the primary health plan payer for 4 patients; MAMSI, 4 patients; and United Healthcare, 8 patients. In its February 2008 filing, JHBMC noted that a few patients are transferred to other hospitals based on insurance dictates

[8] Prince George's Hospital Center does not meet the annual minimum volume requirement for open heart surgical procedures.

and capitation programs. At that time, the hospital also reported that it had "successfully negotiated new third party payor contracts including MAMSI/United Healthcare for the provision of cardiology services."

In 2008, the pPCI volume at JHBMC decreased by nearly 20%, which JHBMC attributed to having one lab available for catheterization for half of each day, or 1/3 the normal capacity. The annual Dx cath volumes, including PCI cases with a diagnostic cardiac cath coded, are normally about 30 cases higher.

The hospital expects to retain 80% of the 455 JHBMC patients transferred for Dx cath to Johns Hopkins Hospital (436) and Union Memorial Hospital (19). The hospital's npPCI application has the unconditional support of all physicians with responsibility for referral patterns and referral policy at JHH. (JHBMC had previously projected a retention rate of 100%.)

The straight line distances between JHBMC and the nearest npPCI hospitals in Maryland are 2.1 miles to JHH; 3.7 miles to UMMC; and 4.4 miles to Union Memorial Hospital. Driving times between these hospitals during non-rush hour and rush hour conditions are 4.5 minutes and 7.7 minutes, respectively, to JHH; 6.2 minutes and 10.6 minutes, respectively, to UMMC; and 10.5 minutes and 17.6 minutes, respectively, to UMH.

Additionally, JHBMC provided estimates of Dx cath referrals from Johns Hopkins Community Physicians (23 to 47); two of the group's four offices are in JHBMC's primary or extended service area. Other primary care practices with offices located within the hospital's primary or extended service area and that submitted supporting letters include: Baltimore Medical Systems (86 to 172); Health and Wellness Matters, Inc. (17); Merritt Medical Center (7); True Care Medical Group (233); and Satpal S. Dang, M.D. (10). The estimated total number of patients who would be referred to JHBMC for diagnostic catheterizations and interventional procedures ranges from 376 to 486.

If every pPCI patient at JHBMC were also a candidate for npPCI, the hospital would need 357 diagnostic cath cases to obtain 80 additional npPCI cases at JHBMC. If none of the pPCI patients were found to be candidates for npPCI, JHBMC would need 397 diagnostic cath cases to obtain 89 additional npPCI cases at the hospital. The number of additional diagnostic cases that JHBMC is expected to accumulate among these multiple sources falls within this range. JHBMC is consistent with this requirement.

SUMMARY AND RECOMMENDATION

The Commission has emphasized that waivers to participate in the research study are strictly limited to the research participation. No patients may receive non-primary angioplasty at these sites unless they are enrolled in the research study and randomized to receive angioplasty at the waiver hospital. Unless extended by a vote of the Commission, each research waiver expires at the earliest of the following: 2 years from the date on which the waiver was first issued; the date patient accrual into the C-PORT E study ends; when the Commission finds that the study is not accruing patients at an acceptable rate; or when the Commission finds that the study is unlikely to produce reliable results to guide public policy. The results of this study will inform subsequent revisions of the State Health Plan. If, based on the evidence from this and other

studies, a later revision of the State Health Plan were to recommend issuance of waivers or certificates of need allowing the performance of non-primary angioplasty without cardiac surgery on-site, the criteria applied in that review would be different than the criteria used to identify participants in a research study.

The ability of an applicant for an npPCI waiver to perform least 200 PCIs in the second year of the project is a key requirement for several reasons. First, the ability of a hospital to serve as a site for this research project is highly dependent on the volume of npPCI cases that the hospital will enroll over the course of the study. Second, because this is a time-limited study, required volumes must be achieved quickly (i.e., by Year 2 of the waiver). It is important to select waiver participants that have institutional resources readily available and a strong referral base likely to generate required volumes without an extended ramp-up period.

Executive Director's Recommendation

The Commission's emergency regulations provide for up to three additional or a total of nine waiver recipients. The Commission adopts the Executive Director's Recommendation that the Commission grant a non-primary PCI research waiver to each of the three pending applicants.